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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/698,117	10/31/2003	William J. Bertrand	M190.247.101 / P0011522.0	8914
7590 12/23/2009 Dicke, Billig & Czaja, PLLC ATTN: MD Matters Fifth Street Towers, Suite 2250 100 South Fifth Street Minneapolis, MN 55415			EXAMINER HARRIS, CARRIE R	
			ART UNIT 3735	PAPER NUMBER
			MAIL DATE 12/23/2009	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/698,117	Applicant(s) BERTRAND ET AL.	
	Examiner Carrie Harris	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-7 and 18-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 31 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>31 October 2003 and 9 April 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1-17 in the reply filed on 1 October 2009 is acknowledged. Claims 1-7 and 18-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim.
2. Applicant's election of Species B with traverse of the requirement for an election of species regarding Species B and Species C in the reply filed on 1 October 2009 is acknowledged. The traversal is on the ground(s) that there is no distinctness between Species B and Species C. This is found persuasive. Claims 8-17 are currently under consideration.
3. Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between Species B and C of Invention I as set forth in the Office action mailed on 1 September 2009 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of

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35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

Information Disclosure Statement

4. The information disclosure statement filed 9 April 2007 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

Drawings

5. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: L, W, A, 16, 18, 20, 22, 24, 68, 603, 620, 702, 703, 705, 720, 801, and 811. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37

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CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

6. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: 536. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. **Claims 13-17** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 recites the limitation "the electronic compass module" in lines 6-7.

There is insufficient antecedent basis for this limitation in the claim.

Claims 14-17 are rejected as they are dependent on rejected claim 13.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. **Claims 8, 10-13, and 15-17** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0022793 (Bertrand et al.) in view of U.S. Patent No. 6,305,381 (Weijand et al.).

Regarding **claim 8**, Bertrand et al. teaches an electronic magnetic-based indicator tool comprising: a housing (*Figure 10, indicator central body, 60*) having a connection to a locator tool (*Figure 4, locator tool, 26*) (Indicator central body of the indicator tool is placed within the tube of the locator tool, [0059]); a compass module (*Figure 12, compass, 62*) for determining an orientation of sensed magnetic fields ([0053]; [0060]); and a locator tool interface (*Figure 9, index, 88*) communicating sensed magnetic field data to the user after receiving magnetic data values from the compass module (*compass, 62*) ([0058]; [0060]); wherein the locator tool (*locator tool, 26*) necessarily receives background magnetic field data (When the indicator tool is in use as part of the locator tool, the compass necessarily detects ambient magnetic fields.);

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receives target magnetic field data when the indicator tool (*Figure 9, indicator tool, 28*) is located above an implanted flow control device having a magnetic indicator device (*Figure 1, magnet, 20*) coupled to a valve (*Figure 1, valve, 10*) ([0010]; [0060]); and determines a setting for the valve (*valve, 10*) within the implanted flow control device using the background magnetic field data and target magnetic field data ([0060]).

Bertrand et al. does not teach that the indicator tool comprises an electronic processor.

However, Weijand et al. teaches an electronic magnetic-based indicator tool comprising: a housing having an electric connection to a locator tool (*Figures 1 and 4, array, 3 and processor, 2*) (col. 2, lines 44-47; col. 3, lines 17-19; see *Figures 1 and 4*; device necessarily has a housing containing an electrical connection between the array and processor); an electronic compass module (*Figures 1 and 4, antennas, 30-32*) for determining an orientation of sensed magnetic fields (col. 3, lines 31-35 and lines 43-52); and a locator tool interface module (*Figure 4, switch, 50, amplifier, 51, and computer, 53*) for communicating sensed magnetic field data to a processing module (*Figure 4, microprocessor, 54*) in the locator tool (*array, 3 and processor, 2*) for receiving magnetic data values from the electronic compass module (*antennas, 30-32*) (col. 3, line 56-col. 4, line 13); wherein the processing module (*microprocessor, 54*) necessarily receives background magnetic field data (Ambient magnetic fields are necessarily detected by the array and processor if they are present.); receives target magnetic field data when the indicator tool is located above an implanted device (*Figure 1, medical device, 4*) having a magnetic indicator device (*Figures 1 and 4, implanted coil, 22*) (col. 2, lines 44-50; col. 3, lines 31-35 and lines 43-52). It would have been

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obvious to one of ordinary skill in the art at the time of the invention to modify the mechanical indicator tool of Bertrand et al. to have an electronic detection and processing system for detecting the location and orientation of the magnetic field emitted by the implanted medical device similar to that of Weijand et al., because an electronic detection and processing system provides a noninvasive, automated mechanism which reduces the potential for human error in detecting the location and orientation of an implanted medical device.

Regarding **claim 10**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 8 above. Bertrand et al. teaches that the indicator tool (*Figure 10, indicator tool, 28*) further comprises a mechanical key device (*Figure 10, ridge, 70*) about its housing for orientating the indicator tool (*indicator tool, 28*) into a desired position relative to a locator tool (*Figure 4, locator tool, 26*) placed in a desired orientation relative to the implanted flow control device ([0054]; [0070]-[0071]).

Regarding **claim 11**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 8 above. Bertrand et al. teaches that the indicator tool (*Figure 10, indicator tool, 28*) corresponds to a handheld device ([0014]).

Regarding **claim 12**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claim 11 above. Bertrand et al. and Weijand et al. teach that the handheld device includes a removable battery (Weijand et al., *Figure 1, battery, 21*) (The battery is necessarily able to be removed from the remainder of the device, Weijand et al., col. 64-67).

Regarding **claim 13**, Bertrand et al. teaches an electronic magnetic-based indicator tool comprising: a housing (*Figure 10, indicator central body, 60*) having a connection to a locator tool (*Figure 4, locator tool, 26*) (Indicator central body of the indicator tool is placed within the tube of the locator tool, [0059]); a compass module (*Figure 12, compass, 62*) for determining an orientation of sensed magnetic fields ([0053]; [0060]); and a locator tool interface (*Figure 9, index, 88*) communicating sensed magnetic field data to the user after receiving magnetic data values from the compass module (*compass, 62*) ([0058]; [0060]); wherein the locator tool (*locator tool, 26*) necessarily receives background magnetic field data (When the indicator tool is in use as part of the locator tool, the compass necessarily detects ambient magnetic fields.); receives target magnetic field data when the indicator tool (*Figure 9, indicator tool, 28*) is located above an implanted flow control device having a magnetic indicator device (*Figure 1, magnet, 20*) coupled to a valve (*Figure 1, valve, 10*) ([0010]; [0060]); and determines a setting for the valve (*valve, 10*) within the implanted flow control device using the background magnetic field data and target magnetic field data ([0060]).

Bertrand et al. does not teach that the indicator tool comprises an electronic processor.

However, Weijand et al. teaches an electronic magnetic-based indicator tool comprising: a housing having an electric connection to a locator tool (*Figures 1 and 4, array, 3 and processor, 2*) (col. 2, lines 44-47; col. 3, lines 17-19; see *Figures 1 and 4*; device necessarily has a housing containing an electrical connection between the array and processor); a target compass module (*Figures 1 and 4, antennas, 30-32*) for determining an orientation of sensed magnetic fields (col. 3, lines 31-35 and lines 43-

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52); a locator tool interface module (*Figure 4, switch, 50, amplifier, 51, and computer, 53*) for communicating sensed magnetic field data to a processing module (*Figure 4, microprocessor, 54*) in the locator tool (*array, 3 and processor, 2*) for receiving magnetic data values from the electronic compass module (*antennas, 30-32*) (col. 3, line 56-col. 4, line 13); wherein the processing module (*microprocessor, 54*) necessarily receives background magnetic field data from a background compass module within the locator tool (*array, 3 and processor, 2*) (Ambient magnetic fields are necessarily detected by the array and processor if they are present. The target and background compass modules are considered part of the antennas as these antennas necessarily detect any electromagnetic fields within the vicinity of the device, and send the sensed data to the processor.); receives target magnetic field data when the indicator tool is located above an implanted device (*Figure 1, medical device, 4*) having a magnetic indicator device (*Figures 1 and 4, implanted coil, 22*) (col. 2, lines 44-50; col. 3, lines 31-35 and lines 43-52). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the indicator tool of Bertrand et al. to have an electronic detection and processing system for detecting the location and orientation of the magnetic field emitted by the implanted medical device similar to that of Weijand et al., because an electronic detection and processing system provides a noninvasive, automated mechanism which reduces the potential for human error in detecting the location and orientation of an implanted medical device.

Regarding **claim 15**, see discussion for claim 10.

Regarding **claim 16**, see discussion for claim 11.

Regarding **claim 17**, see discussion for claim 12.

11. **Claims 9 and 14** are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application No. 2002/0022793 (Bertrand et al.) in view of U.S. Patent No. 6,305,381 (Weijand et al.) as applied to claims 8 or 13 above, and further in view of U.S. Patent No. 5,136,242 (Abraham-Fuchs).

Regarding **claims 9 and 14**, Bertrand et al. in view of Weijand et al. teaches all the limitations of claims 8 and 13 above. Bertrand et al. and Weijand et al. teach that the device necessarily detects background magnetic field data as well as target magnetic field data, but does not teach that the background data is subtracted from the target data.

However, Abraham-Fuchs teaches a device for detecting the magnetic field emanating from a source in a patient's body comprising a processing module (*Figure 1, computer, 9*) subtracts measured background magnetic field data from measured target magnetic data to determine the location of the true target magnetic data (col. 1, lines 43-53; col. 2, lines 14-20 and lines 35-38; col. 3, lines 17-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the processing module of Bertrand et al. and Weijand et al. to subtract the background magnetic field data from the target magnetic field data to localize the target as taught by Abraham-Fuchs, because subtracting background magnetic field data from target magnetic field data prevents a false localization of the target magnetic field (Abraham-Fuchs, col. 3, lines 17-20 and lines 47-48).

Conclusion

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carrie Harris whose telephone number is (571) 270-7483. The examiner can normally be reached on Monday - Friday from 8 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735

/C. H./
Examiner, Art Unit 3735